NOV 2 7 2000

K003069

510(k) SUMMARY

Applicant: Quest International, Inc.
1938 N.E. 148th Terrace
North Miami, FL 33181

Registration No. 1061839

Contact Person: Robert A. Cort, V.P. , Quality Assurance

Telephone: (305) 948-8788

Telefax: (305) 948-4876

Manufacturing Site: Same as above

Device: SeraQuest® Anti-Cardiolipin IgG

Device Name: Anti-Cardiolipin, Multiple autoantibodies immunological test system (21CFR § 866.5660)

Device Classification: Class II (Performance Standards)

Description:

The SeraQuest Anti-Cardiolipin IgG test is a solid-phase enzyme immunoassay (EIA), which is performed in microwells, at room temperature, in three thirty minute incubations. It has been developed to detect IgG antibodies which are directed against cardiolipin, in human serum.

The Calibrators in the SeraQuest Anti-Cardiolipin IgG test kit have been assigned values based on the Harris standards. Test results are reported as GPL units per milliliter (GPL U/mL).

Principle:

Diluted samples are incubated in wells coated with Cardiolipin antigen. Antibodies directed against Cardiolipin antigen (if present) are immobilized in the wells. Residual sample is eliminated by washing and draining, and conjugate (enzyme-labeled antibodies to human IgG) is added and incubated. If IgG antibodies to Cardiolipin antigen are present, the conjugate will be immobilized in the wells. Residual conjugate is eliminated by washing and draining, and the enzyme substrate is added and incubated. In the presence of the enzyme, the substrate is converted to a yellow end-product which is read photometrically at 405 nm.

Intended Use:

Intended Use: The Anti-Cardiolipin IgG test is intended for the quantative detection of human IgG antibodies to cardiolipin antigen, in human serum by enzyme immunoassay. The presence of anti-ırdiolipin antibodies can be used with other serological tests and clinical findings to aid in

ssessing the risk of thrombosis in individuals with systemic lupus erythematosus (SLE) or lupus-like disorders. For In Vitro Diagnostic Use Only.

Predicate Device:

The SeraQuest Anti-Cardiolipin IgG test is substantially equivalent in intended use and performance, to the QUANTA Lite ACA IgG (HRP) test, INOVA Diagnostics, Inc. 10180 Scripps Ranch Boulevard, San Diego, CA.

Summary of Technological Characteristics:

Characteristic	SeraQuest Anti-Cardiolipin IgG Test	INOVA Diagnostics QUANTA Lite ACA IgG Test
Description:	Enzyme Immunoassay	Enzyme Immunoassay
Intended Use:	The detection of IgG antibodies against cardiolipin in human serum.	The detection of IgG antibodies against cardiolipin in human serum.
Solid Phase:	Polystyrene Microwell	Polystyrene Microwell
ntigen :	Purified Cardiolipin (bovine heart)	Purified Cardiolipin
Number of Incubation Periods:	Three	Three
Sample Dilution:	1:51	1:101
Sample Incubation Duration:	30 minutes	30 minutes
Incubation Temperature:	Room temperature	Room temperature
Ezyme-labeled Conjugate:		
Antibody	Goat anti-human IgG	Goat anti-human IgG
Enzyme	Alkaline phosphatase	Horse Radish Peroxidase
Conjugate Volume:	100 µl	100 µl
Conjugate Incubation uration:	30 minutes	30 minutes

Substrate:	p-Nitrophenyl phosphate	TMB
Subtrate Volume:	100 µl	100 µl
Substrate Incubation Duration:	30 minutes	30 minutes
Stop Reagent:	0.5 M Trisodium phosphate	0.34 M Sulfuric acid
Stop Reagent Volume:	100 µl	100 µl
Readout:	Spectrophotometric	Spectrophotometric
Wavelength: Reference Wavelength:	405 nm 620 nm	450 nm 620 nm
Normalization:	Standard Curve	Standard Curve
Reporting Unit:	GPL Units / mL	GPL Units / mL

Summary of Clinical Testing:

Experimental Procedure

To challenge the cutoff values, 88 serum specimens were tested at Quest International, Inc., concurrently by the SeraQuest Anti-Cardiolipin IgG test, and the QUANTA Lite ACA IgG test (INOVA Diagnostics). The test specimens included: 53 obtained from rheumatology patients, and 35 reported to contain anti-cardiolipin antibodies, which were obtained from serum brokers. The assays were performed and interpreted according to the instructions in the manufacturer's package inserts.

Results and Conclusion

The qualitative agreement between the SeraQuest and the INOVA tests is shown in Table 1.

Of the 88 specimens tested, 24 were positive, and 46 were negative in both the SeraQuest and INOVA tests . Of the 18 specimens remaining, 6 specimens which were negative by the INOVA test, were positive by the SeraQuest test, and 6 specimens which were positive by the INOVA test, were negative by the SeraQuest test. Six specimens which were equivocal in the SeraQuest test, were negative by the INOVA test. The latter test has no equivocal interpretation.

Excluding the equivocal results, the sensitivity of the SeraQuest Anti-Cardiolipin IgG test relative to the INOVA QUANTA Lite ACA IgG test was 80.0 %, or 65.7 % to 94.3 % (95% C.I.); the specificity was 88.5 %, or 79.8 % to 97.1 % (95% C.I.); respectively. The overall agreement was 85.4%, or 77.7 to 93.0% (95% C.I.) (please see Table 1).

TABLE 1.

RESULTS OF SeraQuest® ANTI-CARDIOLIPIN IgG ASSAYS, AND INOVA QUANTA-LITE ACA IgG ASSAYS OF 88 SERUM SPECIMENS.

	SeraQuest RESULTS					
INOVA RESULTS	**Positive**	**Negative**	**Equivocal**			
					%	**95% CI√**
Positive	**24**	**6**	**0**	**Relative Sensitivity**	**80.0**	**65.7 to 94.3**
Negative	**6**	**46**	**6**	**Relative specificity***	**88.5**	**79.8 to 97.1**
				Overall agreement*	**85.4**	**77.7 to 93.0**

*** Excluding equivocal results.**
√ 95%Confidence Interval calculated by the normal method.

Seven negative or weakly positive specimens yielded discordant results. When these specimens were re-tested using another legally marketed device, the SeraQuest results were confirmed in five instances, and the Quanta-Lite ACA results supported in seven cases.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 2 7 2000

Mr. Robert A. Cort
Vice President, Quality Assurance
Quest International, Inc.
1938 N.E. 148th Terrace
North Miami, Florida 33181

Re: K003069
Trade Name: SeraQuest Anti-Cardiolipin IgG
Regulatory Class: II
Product Code: MID
Dated: September 21, 2000
Received: October 2, 2000

Dear Mr. Cort:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

APPENDIX 6

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510(k) Number (if known): K003069

Device Name: SeraQuest Anti-Cardiolipin IgG

Indications For Use:

1. For in vitro diagnostic use only.

2. For the qualitative and quantitative detection of IgG antibodies to cardiolipin in human serum by enzyme immunoassay.

3. May be used in conjunction with other serological tests and clinical findings to aid in assessing the risk of thrombosis in individuals with systemic lupus erythematosus (SLE), or lupus-like disorders.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maden

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003069

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)